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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/630,000      | 08/01/2000  | Bruce Tockman        | 279.246US1          | 8111             |

21186 7590 03/17/2004

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 03/17/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/630,000

Applicant(s)

TOCKMAN ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-46 is/are pending in the application.
- 4a) Of the above claim(s) 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-26 and 43-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 27-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 5.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "coradial" is not used in the specification.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 16-20, 24, 26, 43, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelsson et al (6249708).

Nelson discloses the claimed invention and the use of different types of conductors, (multifilar, unifilar, any combination of the two, DBS) individually insulated and wound except for the different conductors being different materials, wherein the first material has a different stiffness than a second material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials, wherein the first material has a different stiffness than a second material since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide different and required impedance/resistances, different current carrying capabilities, and/or different flexibility/stiffness to the lead. In addition, it is inherent that the different conductors will have different electrical properties.

Claims 21-23, 25, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.

Nelson discloses the claimed invention but does not disclose expressly the first material being MP35N and the second material being Pt/Ta (claims 21 and 22), one of the conductors having a heat setting capability (claim 25), and the first conductor disposed only in the second and third sections (claims 23 and 44). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Nelson with the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections, because Applicant has not disclosed that the first material being

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MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any two different materials having different stiffness for the conductors and the termination of the first conductor at its respective electrode and connector as taught by Nelson in view of one having ordinary skill in the art, because it would provide a lead having different conductors with different stiffness to provide required current carrying capabilities and/or different flexibility/stiffness to the lead and provide the needed length of the first conductor to provide electrical therapy or sensing to the electrode.

Therefore, it would have been an obvious matter of design choice to modify Nelson to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with a conductor having heat setting capabilities since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration.

Claims 16-20, 24, 43, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr. et al (5935159).

Cross discloses the claimed invention and the use of different types of conductors, (stranded, coiled, having different diameters) individually insulated and wound except for the different conductors being different materials, wherein the first material has a different stiffness than a second material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors

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being different materials, wherein the first material has a different stiffness than a second material since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide different and required impedance/resistances, different current carrying capabilities, and/or different flexibility/stiffness to the lead. In addition, the first conductor extending from a connector ring to an electrode will provide the claimed limitation of the first conductor only extending over the second section. Also, it is inherent that the different conductors will have different electrical properties.

Claims 21-23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr et al.

Cross discloses the claimed invention but does not disclose expressly the first material being MP35N and the second material being Pt/Ta (claims 21 and 22), one of the conductors having a heat setting capability (claim 25), and the lead having a two or three dimensional bias. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Cross with the first material being MP35N and the second material being Pt/TA, because Applicant has not disclosed that the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any two different materials having different stiffness for the conductors as taught by Cross in view of one having ordinary skill in the art, because it would provide a lead

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having different conductors with different stiffness to provide required current carrying capabilities and/or different flexibility/stiffness to the lead.

Therefore, it would have been an obvious matter of design choice to modify Cross to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with a conductor having heat setting capabilities and the lead having a two or three dimensional bias since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration and since it was known in the art that leads are provided with a two or three dimensional bias to allow the lead to be easily located in a particular part of the body and allow the lead to remain in that location.

### ***Response to Arguments***

Applicant's arguments filed 12/22/03 have been fully considered but they are not persuasive. The request for prior art that shows it would be obvious to use conductors of different materials having varying stiffness and electrical properties has previously been met. The last office action provided three teachings (US patents 6253111, 4640983, and 6400992) that show the use of different conductors having different stiffness/properties used in medical leads. In addition, the cited prior art of US patent 5849032 shows the use of a heat setting conductor, nitinol. In addition, the examiner has provided patent 5052407. The argument that the examiner has not stated how the references would be in need of the obvious modifications given in the 103 rejections (that the rejections lack some suggestion of the desirability of doing what the inventor has done) is not persuasive since in each 103 rejection the examiner has

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provided the suggestion for the modification. As an example, in the first 103 rejection given above, the examiner stated that it is known to provide leads with different conductors made of different materials and stiffness "to provide different and required impedances, different current carrying capabilities, and/or different flexibility/stiffness to the lead". The argument that the references do not show the conductors forming a lumen is not persuasive. The conductors do form a lumen, but the lumen is filled with different materials of the lead body. The claim does not state that the lumen is empty.

The argument that the examiner needs to provide references for the 103 rejections based on criticality and that the examiner is taking official notice is not persuasive. The argument that the examiner has a burden to develop a prima facie case of obviousness by providing references which include each limitation of the claims is not persuasive. According to MPEP 2144, sources of rationale supporting a rejection under 35 USC 103 may be in a reference, or reasoned from common knowledge in the art, scientific principles, art recognized equivalents, or legal precedent.

The statement that the applicant requests a reference according to MPEP 2144.03 to support the alleged case of obviousness is not valid. The examiner only needs to provide a reference if there is a reliance on common knowledge in the art or "well known" prior art. The examiner has not made a 103 rejection on common knowledge in the art or "well known" prior art. The examiner is not stating that the 103 rejections are due to common knowledge but stating that the specification has not provided any reasoning or criticality for the claimed elements and lacking such, the examiner does not find patentable subject matter in those limitations. The systems of the prior art operate on basically the same principle and in the same manner as the



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applicant's device. Those limitations which applicant relies on provide no novel or unexpected results and use of such limitations in lieu of those used in the references solves no stated problem and would be an obvious matter of design choice within the skill in the art. (see *In re Kuhle*, 188 USPQ 7 and MPEP 2144.04)

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko  
Primary Examiner  
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3/12/4

GRE  
March 12, 2004